DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#17

AUG 16 1993

Re: PAXIL®
Docket No. 93E-0146

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DEPUTY ASSISTANT
COMMISSIONER FOR PATENTS

The Honorable Michael K. Kirk
Acting Assistant Secretary of Commerce and
Acting Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Kirk:

This is in regard to the application for patent term extension for U.S. Patent No. 4,721,723, filed by Beecham Group p.l.c., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for PAXIL®, the human drug product claimed by the patent.

The total length of the review period for PAXIL® is 3267 days. Of this time, 2132 days occurred during the testing phase and 1135 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 21, 1984.

   The applicant claims January 22, 1984, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 21, 1984, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: November 21, 1989.

   The applicant claims November 29, 1989, as the date the new drug application (NDA) for PAXIL® was initially submitted. However, FDA records indicate that NDA 20-031 was initially submitted on November 21, 1989.

3. The date the application was approved: December 29, 1992.

   FDA has verified the applicant's claim that NDA 20-031 was approved on December 29, 1992.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Edward T. Lentz
Corporate Patents-U.S.-UW2220
SmithKline Beecham Corporation
P.O. Box 1539
King of Prussia, PA 19406-0939